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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,823	11/28/2000	Mark R. Holl	10-98H	7107

23713 7590 02/04/2003
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BOULDER, CO 80303

EXAMINER

BEX, PATRICIA K

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/723,823	HOLL ET AL.	
	Examiner	Art Unit	
	P. Kathryn Bex	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 1-16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "the instrument of claim 1 which is disposable" is not supported within the instant specification. Page 3, last full paragraph states " ..a disposable fluidic hematology cartridge..", not a disposable *sample analysis instrument* for use with a fluidic cartridge.

Claim Objections

2. Claim 1 is objected to because of the following informalities: claim 1, recites in the preamble " having a first analysis regions". Examiner believes this be changed to --having a first analysis region--. Appropriate correction is required.

3. The numbering of claims is incorrect, there are two occurrences of claims 3 and 4.

The second occurrence of claims 3 and 4 has been renumbered 5-6, therefore claim 5 has been changed to claim 7, claim 6 has been changed to claim 8, etc...

For examination purposes, renumbered claim 6 is assumed to depend from claim 5, not claim 3 for proper antecedent basis. Similarly, renumbered claim 7 is assumed to depend from claim 6, not claim 4 for proper antecedent basis. Renumbered claim 10 is assumed to depend from claim 9, not claim 7 for proper antecedent basis. Renumbered claim 12 is assumed to depend from claim 11 not claim 9 for proper antecedent basis. Renumbered claims 14-15 are assumed to depend from claim 13 not claim 11 for proper antecedent basis. Applicant is required to correct the numbering of these depended claims.

Claim Rejections - 35 USC § 112

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 2, recite "said apparatus", it is not clear as to which apparatus Applicant is referring to, i.e. the fluidic cartridge or the sample analysis instrument for use with the fluidic cartridge?

Claim 9, line 2, "said apparatus" creates confusion and uncertainty as to which *apparatus* Applicant is referring to, i.e. the flow cytometric measuring apparatus or the apparatus recited within the preamble? Same deficiency was found in claim 11.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

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reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1-7, 9-11, 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyazaki *et al* (USP 5,370,842).

Miyazaki *et al* teach a sample measuring system. The system includes a disposable flow cytometric cartridge 100 having a micro-channel 7, 56 with micropump 9, 58 and a cartridge holder 101 for holding the cartridge. Additionally, the cartridge includes a sample inlet 5,53, for interface with a pipette or syringe 105 and two different analysis regions. The first analysis region comprising photodetectors 60, 61 to collect light from the analysis region and the second analysis region comprising an electrical measuring apparatus, e.g. two electrodes 63, 64 for measuring the electrical impedance of the particles. Additionally, the light sources 14, 16 or 65, 67 can be a semiconductor laser (column 11, lines 36-51) Miyazaki *et al* disclose the use of sheath fluid to provide for the measurement of individual particles in the sample. (column 10, line 27- column 12, line 59, Fig. 10-11).

9. Claims 1-10, 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Altendorf *et al* (USP 5,726,751).

Altendorf *et al* teach a silicon microchannel optical flow cytometer instrument comprising a cartridge holder 30 for engaging a flow module, or cartridge 10 via clamps 33. The instrument having a flow cytometric measuring device optically coupled to a first analysis region of the flow module. The flow cytometric measuring apparatus having a light source (e.g. laser, column 2, line 2) and a first 120 and second 130 photodetector aligned to collected scattered or fluorescent light from the first analysis region. The cartridge having a pump interface 14 and the

instrument having a syringe pump (column 5, lines 57-58). Moreover, Altendorf *et al* teach a cartridge comprising cartridge alignment markings and the optical head which includes a kinematic mount with contact elements. The cartridge can be connected to the kinematic mount (column 5, line 42- column 6, line 40).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miyazaki *et al* (USP 5,370,842).

Miyazaki *et al* as previously discussed above, do teach the use of valves for controlling the introduction of sample and sheath fluid into the cartridge (115, Fig. 15). However, Miyazaki *et al* do not disclose the specific use of a pinch valve. The use of pinch, check, poppet or squeeze valves are well known for their use in the volumetric fluid transfer art. Moreover, the selection

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of any of these known equivalents to control fluid flow would be within the level of ordinary skill in the art.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have modified the sample analysis system of Miyazaki *et al* within the pinch valve, since it is well known in the art that pinch valves provide reliable fluid control without the need for complicated moving parts.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7-10, 12 of copending Application No. 09/428,839. Although the conflicting claims are not identical, they are not patentably distinct from each other because a sample analysis instrument for use with a fluidic cartridge, the analysis instrument comprising: a disposable cartridge holder, a flow cytometric measuring apparatus positioned to be optically coupled with a first analysis region, a second analysis region comprising electrical measuring apparatus, a pump interface and valve interface.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

15. No claims allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex

P. Kathryn Bex
Patent Examiner
AU 1743
January 23, 2003

Jill Warden
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